

A Response to the Office Action:**A. Comments on the May 6, 2005, Office Action**

The Action indicates that Applicants' Supplemental Response filed on April 25, 2005, was non-compliant because of Applicants' use of the term "previously submitted" in describing claims that were previously submitted to the U.S. Patent Office. Applicants have addressed the Action's concerns by describing previously submitted claims as "previously presented." Applicants request that the amendments and arguments made within this document be considered by the Patent Office.

B. Status of the Claims

Claims 33-36, 38-39, 41-42, and 44-60 were pending when Applicants filed a response with the U.S. Patent Office on January 26, 2005. Claims 33, 39, 42, and 55 have been amended, claim 47 has been canceled, and claims 61-68 have been added. Support for the amendments and new claims can be found throughout the specification and claims as originally filed. Claims 33-36, 38-39, 41-42, and 44-46, and 48-68 therefore are currently pending.

C. Telephone Interview With the Examiner

Applicants representative, Michael R. Krawzenek, and Examiner Jeanine A. Goldberg conducted a telephone interview on April 13, 2005. The present invention, current rejections, and potential amendments to the claims were discussed during the telephone call. No agreement was reached. Examiner Goldberg indicated that she would consider additional amendments in a Supplemental Response to the Office Action. The present document is the "Supplemental Response."

D. The Indefiniteness Rejections Are Overcome

The Action rejects claims 33-43 and 47 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Two separate indefiniteness rejections exist.

Applicants disagree with these rejections. The present claims are definite and satisfy all of the requirements under 35 U.S.C. § 112, second paragraph. Applicants address each rejection separately.

1. Claims 34-35 Are Definite

The Action takes the position that claims 34-35¹ are indefinite because the phrase "suitable for digestion together with said biological sample" is subject to multiple interpretations. Applicants note that this phrase has been deleted. The present indefiniteness rejection is therefore rendered moot, and the rejection of claims 33-34 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

2. Claims 36-43 and 47 Are Definite

Claims 36-43 and 47 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness over the use of the phrase "substantially irreversibly adhered together." The Action contends that this phrase is "relative" which renders the claim indefinite. It appears that the Action is concerned with the term "substantially."

Applicants traverse. The phrase "substantially irreversibly adhered together" is definite and satisfies all of the requirements of 35 U.S.C. § 112, second paragraph. A person of skill in the art would understand the scope of this claim when read in light of the specification. This is confirmed by the MPEP which notes that the term "substantially" is an acceptable claiming term.

¹ Applicants note that claims 33-34 include the disputed language. Claim 35 does not include this language. For the purposes of this response, Applicants will address claims 33 and 34, and not claim 35.

See MPEP § 2173.05(b)(D) (listing cases holding that the use of the term "substantially" in a claim does not make that claim indefinite).

In an effort to further the prosecution in this case and to obtain commercially relevant claims at this time, Applicants have removed term "substantially" from these claims. This rejection should therefore be withdrawn. It is Applicants' position that the claims that no longer recite the term "substantially" are now broader in scope.

E. The Anticipation Rejections Are Overcome

1. Claims 33-35, 40-41, 43, 45-46, and 48-58 Are Not Anticipated by U.S. Patent No. 5,858,770 to Perlman

Claims 33-35, 40-41, 43, 45-46, and 48-58 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,858,770 to Perlman. The Action contends that Perlman teaches a cell culture plate with an oxygen and carbon-dioxide permeable waterproof sealing membrane. It is also contended by the Action that "[t]he microwell plate is suitable for allowing digestion of a biological sample with the plate." The Action, page 6.

Applicants traverse this rejection. Perlman does not anticipate the present claims, either expressly or inherently.

Applicants' independent claim 33, for example, recites "...a base sheet arranged so that a biological sample may be positioned thereon, wherein a portion of the base sheet partially dissolves in a solution...." Independent claim 55 recites "...a base sheet arranged so that the biological sample may be positioned thereon, the base sheet comprising an absorbent material that is secured to a portion of a front surface of the base sheet...." These elements do not appear to be disclosed or suggested by Perlman. Additionally, this reference appears to fail to disclose other claimed elements. For example, there does not appear to be any disclosure of a "sheet comprising an adhesive that contacts the biological sample and the base sheet to enclose the

biological sample between the transparent polymeric sheet and a side of the base sheet that is indicia free." Claim 33; *see also* claim 55.

Rather, Perlman appears to disclose a cell culture plate that can be used for culturing and manipulating living cells. *See* Perlman, col. 1, lines 6-11. The cell culture plates can be sealed with an oxygen and carbon dioxide-permeable waterproof sealing membrane. *Id.* The membrane allows living cells "to grow and survive within a sealed leak-proof culture plate." *Id.* at col. 2, lines 5-6.

Because Perlman does not teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-35, 40-41, 43, 45-46, and 48-58 should therefore be withdrawn.

2. Claims 33-36, 38-39, and 41-47 Are Not Anticipated By U.S. Patent No. 3,733,025 to Hiersteiner

The Action rejects claims 33-36, 38-39, and 41-52 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,733,025 to Hiersteiner. The Action contends that this reference discloses an envelope which has a tamper-evident storage means for storing a sample. The Action also states that the envelope has a backing sheet which is releasably secured to the surface of the cover sheet facing the base sheet.

Applicants traverse. Hiersteiner does not anticipate claims 33-39 and 41-47, either expressly or inherently.

Hiersteiner does not appear to disclose "a transparent polymeric sheet" or a "transparent cover sheet." See claims 33 and 55. Additionally, this reference also apparently fails to disclose a "sheet comprising an adhesive that contacts the biological sample and the base sheet to enclose the biological sample between the transparent polymeric sheet and a side of the base sheet that is indicia free." Claim 33; *see also* claim 55.

Rather, this reference appears to disclose a standard office envelope. The envelope appears to include a seal flap that:

... has a portion reinforced by folding an adhesive connection, the reinforced portion being divided from the remainder of the seal flap by a line of tear perforations. A releasable adhesive connection is made between the outside of said portion and the back of the envelope whereby said portion may be peeled across the back of the envelope to open the same.

See Hiersteiner, Abstract. As noted above, this reference does not appear to disclose at least the above cited elements. The anticipation rejection therefore cannot be maintained.

Applicants request that the rejection of claims 33-39 and 41-47 as being anticipated by Hiersteiner be withdrawn.

3. Claims 33-35, 41, and 43-47 Are Not Anticipated By U.S. Patent No. 3,965,888 to Bender

The Action rejects claims 33-35, 41, and 43-47 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,965,888 to Bender. The Action contends that this reference discloses a specimen collector and holder. It further contends that the holder includes a transparent foldable segment that is used to collect the specimen and retain the back-folded segment for visual examination.

Applicants traverse. Bender does not anticipate claims 33-35, 41, and 43-47, either expressly or inherently.

Bender appears to disclose “[a] specimen holder ... for collecting and examining a specimen collected from a body.” Bender, Abstract. This reference appears to disclose a plastic layer that is folded back on itself. *Id.* at FIGS 6 and 7.

This reference does not appear to disclose Applicants’ claimed element of “a transparent polymeric sheet secured to the base sheet, the transparent polymeric sheet comprising an adhesive that contacts the biological sample and the base sheet to enclose the biological sample

between the transparent polymeric sheet and a side of the base sheet....". Claim 33; *see also* claim 55. Additional elements that do not appear to be disclosed by this reference include "wherein the storage structure allows at least partial digestion of the biological sample." Claims 33 and 55. There also does not appear to be any disclosure of a base sheet "comprising an absorbent material that is secured to a portion of a front surface of the base sheet." Claim 55.

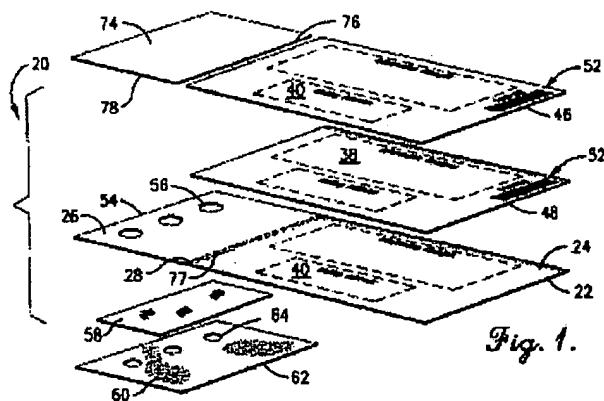
Because the cited reference does not appear to teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-35, 41, and 43-47 should therefore be withdrawn.

4. Claims 33-36, 38-39, and 42-52 Are Not Anticipated By U.S. Patent No. 6,007,104 to Draper

The Action rejects claims 33-36, 38-39, and 42-52 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,007,104 to Draper. The Action contends that this reference discloses a multilayer medical device and form for collecting samples and retaining information. The Action states that the left side of the device can take samples and the right side includes insurance and individual information. According to the Action, the device contains a base sheet and a cover sheet with an adhesive.

Applicants traverse. Draper does not anticipate claims 33-36, 38-39, and 42-52, either expressly or inherently.

Draper appears to disclose "[a] combined medical device and form (20) having a unitary substrate (22) which is divided into a medical device portion (24) and a form portion (26). The form portion (24) of the substrate includes an informational section (30, 32, 34), and form identification material (36)." Draper, Abstract. Additionally, FIG. 1 of this reference indicates that the biological sample is not enclosed:



Id. at FIG. 1. This is confirmed by the specification which recites:

of the perimeter 54 of the medical device portion 26. The
 25 securement sheet 60 also includes three blood application
 openings 64 which are aligned with the blood application
 openings 56 of the substrate 22 to expose both sides of the
 blood application sheet 58. The blood application openings
 30 56 of the substrate 22 are preferably larger than the blood
 application openings 64 of the securement sheet 60 to assure
 alignment in an automated assembly process, and the open-
 35 ings 56 are further sized to allow blood to dry in the blood
 application sheet 58 while inhibiting contact between the
 blood application sheet 58 and any surface on which the
 DBS packet rests. Thus, the small openings inhibit contami-
 nation.

Id. at col. 4, lines 23-35. The openings 64 appear to allow the "blood to dry in the blood application sheet 58...." *Id.* at lines 31-32. Stated another way, it appears that the blood is not enclosed, it is exposed to allow the blood to dry. *See id.*

By contrast, Applicants claim "...an adhesive that contacts the biological sample and the base sheet to enclose the biological sample between the transparent polymeric sheet and a side of the base sheet...." Claim 33 (emphasis added); *see also* claim 55. This element does not appear to be disclosed by Bender.

Because Bender does not appear to disclose element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-36, 38-39, and 42-52 should therefore be withdrawn.

F. Submission of A Supplemental Information Disclosure Statement (SIDS)

Applicants are also filing an SIDS concurrently with this paper. The references identified in this SIDS do not appear to disclose every element of the present invention. For example, these references do not appear to disclose:

...a transparent polymeric sheet secured to the base sheet, the transparent polymeric sheet comprising an adhesive that contacts the biological sample and the base sheet to enclose the biological sample between the transparent polymeric sheet and a side of the base sheet that is indicia free...

Claim 33.

...a transparent cover sheet secured to the base sheet, the transparent cover sheet comprising an adhesive that contacts the biological sample and the base sheet to enclose the biological sample between the transparent cover sheet and the front surface of the base sheet...

Claim 55.

These and other aspects of the independent and dependent claims do not appear to be disclosed by the references listed in the SIDS.

G. Conclusion

Applicants believe that this response places this case in condition for allowance and such favorable action is requested.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3020 with any questions, comments or suggestions relating to this patent application.

Respectfully submitted,



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